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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,678	12/07/2001	Glenn J. Gormley	19109DE	1340
210	7590	03/23/2006	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER
			1618	
DATE MAILED: 03/23/2006				

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/010,678  
Filing Date: December 07, 2001  
Appellant(s): GORMLEY ET AL.

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Catherine D. Fitch  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 12/16, 2005 appealing from the office action mailed May 6, 2005. Thus, the instant office action(Examiner's Answer) supercedes any previous office action.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal, other than the earlier appeal in the present application, Appeal No. 2004-0543, decision mailed December 29, 2004.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

US5,407,944

GOLDMAN

4-1995

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 28-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman (US 5407944).

Claim 28 is directed to a method of treating androgenic alopecia consisting essentially of transversally administering to a person in need of such treatment a therapeutically effective amount of a 5  $\alpha$ -reductase 2 inhibitor; claim 30 specifies administration by transdermal skin patch; claim 33 specifies that the 5  $\alpha$ -reductase 2 inhibitor is 17 $\beta$ -(N-tert-butylcarbamoyl)4-aza-5 $\alpha$ -androst-1-ene-3-one), otherwise known as "Finasteride" ;claim 36 is directed to a skin patch consisting essentially of a 5  $\alpha$ -reductase 2 inhibitor.

Goldman(US'944, hereinafter) teaches that androgenic alopecia/male pattern baldness can be treated topically or systemically with a combination of three agents: a vasodilator; an estradiol; and 5  $\alpha$ -reductase inhibitor(column 2, lines 42-46; column 6, lines 5-9), "A highly preferred inhibitor of ....5  $\alpha$ -reductase for use in [Goldman's] compositions and methods" (column 5, lines 43-44), indeed the only 5- $\alpha$ -reductase inhibitor specifically mentioned, is finasteride(column 5, lines 43-62). While " each agent of the combination need not be administered in the same manner"(column 2, lines 65-67), "in a highly preferred embodiment the selected agents are administered from a

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single vehicle in unit dosage form, including tablet, capsule, and transderma patches or preparation”(column 3, lines 7-10).

While Goldman does not specifically describe incorporating a 5  $\alpha$ -reductase inhibitor into a transdermal skin patch and using the patch to treat androgenic alopecia, he explicitly suggests doing just that. Moreover, Goldman identifies finasteride as a “highly preferred” 5  $\alpha$ -reductase inhibitor for this purpose. The therapeutic effectiveness of finasteride for hair growth (e.g. alopecia(baldness) treatment) is well known in the field as evidenced by numerous documents conventionally\* known in the art at the time of the invention was made(\*see PTO-892, for example Ramusson(EP0285382) . It would have been obvious for one skilled in the art to have treated androgenic by transdermal administration of a pharmaceutical preparation, e.g. a transdermal skin patch, consisting essentially of a 5  $\alpha$ -reductase inhibitor, e.g. finasteride, in view of Goldman’s explicit suggestions.

#### **(10) Response to Argument**

##### **“Consisting Essentially Of”**

Applicants amend the claims and argues that the pending claims 28-37 are patentably distinguished over Goldman in view of the transition phrase “consisting essentially of”(Request for reconsideration and withdrawal of the rejection, see Remark section at page 6, filed 1/31/05 ). According to applicants, the recitation of the claimed language in claims “consisting essentially of 5  $\alpha$ -reductase inhibitor (claims 28-32) or finasteride (claim 33-37)” exclude a vasodilator or an estradiol as active agent taught in Goldman’s teaching.

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The examiner disagree.

As stated in PPG Indus., Inc. V. Guardian Indus. Corp., 156 F 3d 1351, 1355, 48 USPQ 2d 1351, 1353-1354(Fed. Cir. 1998),

By using the term “consisting essentially of,” the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A “consisting essentially of” claim occupies a middle ground between closed claims that are written in a “consisting of” format and fully open claims that are drafted in a “comprising” format.(Emphasis added).

Here, applicants’ argument that “consisting essentially of” excludes those vasodilator or estradiols of Goldman is an example of ipse dixit reasoning. Applicants do not describe the “basic and novel properties of the invention,” or explain why or establish how the vasodilators or estradiols of Goldman materially affects those properties. The therapeutic effectiveness of 5  $\alpha$ -reductase inhibitor (e.g. finasteride) as an active ingredient for hair growth (e.g.alopecia(baldness) treatment) is already well known in the field as evidenced by numerous documents conventionally\* known in the art at the time of the invention was made(\*see previous PTO-892s, for example Ramusson (EP0285382)) .

Additionally, it is apparent from applicant’s specification(pages 7-9) that the composition of the claimed method may include a host of ingredients or additives. On this record, it is unclear why the vasodilators or estradiols of Goldman would “materially affect” the basic and novel properties of the invention and, accordingly, be excluded by the phrase “consisting essentially of,” whereas the host of ingredients listed in the specification do not materially affect the basic and novel properties of the invention and, accordingly, are included by the phrase “consisting essentially of.” Applicants have not

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made it clear, in their specification or in their request for reconsideration, what they "regarded as constituting a material change in the c the basic and novel properties of the invention."

For the reasons above, the claimed subject matter is not patentably distinct from the prior art of the record.

**(11) Related Proceeding(s) Appendix**

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

  
**VICKIE KIM**  
**PRIMARY EXAMINER**

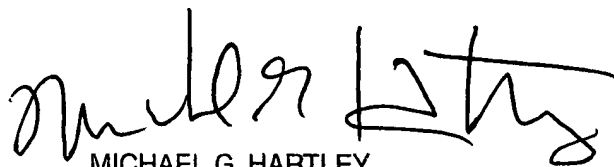
Vickie Kim

Primary Patent Examiner  
Art Unit 1618  
Date: March 17, 2006

Conferees:

Michael Hartley, SPE (GAU: 1618)

Zohreh Fay, Primary Patent Examiner (GAU:1618)

  
**MICHAEL G. HARTLEY**  
SUPERVISORY PATENT EXAMINER

  
**ZOHREH FAY**  
**PRIMARY EXAMINER**  
**GROUP 1600**